SUMMARY OF THE OFFICE ACTION

Claims 1 – 10 are pending in the application.

Claims 1 – 10 are rejected.

The specification is objected to by the Examiner.

The drawings are objected to by the Examiner.

THE CLAIMED INVENTION

As defined by claims 1 and 2, as currently amended, the present invention provides a pelvis frame for hip-replacement surgery on a patient, comprising (a) a first rigid elongated member; (b) a second rigid elongated member mounted on the first rigid elongated member in a perpendicular relationship thereto; (c) first and second pads attached to the first rigid elongated member in a perpendicular configuration; (d) a third pad attached to the second elongated member in a perpendicular configuration; and (e) means for varying position of the first, second, and third pads, and for fixating said position as required, for effecting orientation-determining contact of the first, second, and third pads with pelvic bone of the patient. The first, second, and third pads are contoured to conform to portions of the pelvic bone which the pads contact. The first and second pads are contoured to conform to the anterior superior iliac spines, and the third pad is contoured to conform to the public symphysis. The first and second pads are concave, and the third pad is saddle-shaped.

As defined by claim 3, as currently amended, the invention provides a pelvis level for hip-replacement surgery on a patient. The pelvis level comprises (a) a housing which includes first and second parallel straight-line openings extending therethrough, for insertion therein of first and second wires used to effect temporary connection of the housing to pelvic bone of the patient; and (b) a circular level, disposed in the housing under a transparent cover, for determination of a level position of the housing along both longitudinal and lateral axes.

As defined by claim 5, as currently amended, the circular level comprises a ball disposed under the transparent cover.

As defined by claims 7 and 8, as currently amended, the present invention provides a method for determining the orientation of the pelvic bone of a patient undergoing hip-replacement surgery. The method comprises the following steps: (a) providing a pelvis frame comprising a first rigid elongated member; a second rigid elongated member mounted perpendicularly on the first rigid elongated member; first and second pads attached perpendicularly to the first rigid elongated member; a third pad

attached perpendicularly to the second rigid elongated member; and means for varying position of the first, second and third pads, and for fixating said position as required, for effecting orientation-determining contact of the first, second, and third pads with the patient undergoing the surgery, the first, second, and third pads being contoured to conform to portions of the pelvic bone which said pads contact, the first and second pads being contoured to conform to anterior superior iliac spines, and the third pad being contoured to conform to pubic symphysis; (b) providing a pelvis level comprising a housing which includes first and second parallel straight-line openings extending therethrough, for insertion therein of first and second wires used to effect temporary connection of the housing to pelvic bone of the patient, and a circular level including a crosshair and a bubble or a ball, disposed in the housing under a transparent cover, for determination of a level position of the housing along both longitudinal and lateral axes; (c) adjusting the pelvis frame so that the first and second pads rest on the anterior superior iliac spines of the patient undergoing the surgery; (d) adjusting the pelvis frame so that the third pad rests on the pubic symphysis of the pelvic bone of the patient undergoing the surgery; (e) drilling first and second wires into the anterior superior iliac spines through first and second openings in the first or second pad contacting the anterior superior iliac spine on the side on which the surgery is to be performed; (f) removing the pelvis frame from contact with the patient; (g) turning the patient from back contact to side contact with an operating-room bed; (h) beginning the hip-replacement surgery; (i) at a point during the surgery that acetabular component in the pelvic bone is to be replaced, sliding the pelvis level over the first and second wires through the first and second openings in the first or second pad on the side on which the surgery is being performed; (j) adjusting position of the operating-room bed as required until the bubble or the ball indicates level position; (k) adjusting the position of the operating-room bed until the crosshair indicates level position; and (l) replacing the acetabular component in the pelvic bone. The first and second pads are concave, and the third pad is saddle-shaped.

As defined by claim 9, as currently amended, the circular level comprises a ball disposed under the transparent cover.

SCOPE OF THE PRIOR ART

U.S. Patent (U.S.P.) 5,141,512 to Farmer et al. discloses an apparatus for aligning an acetabular cup for proper placement in a socket in hip joint replacement. The apparatus includes a frame having feet which are placed against and fastened to the anterior superior iliac spines and the pubic tubercles respectively of the pelvis. A light beam is directed from a source through an aperture to a mirror mounted on an implant inserter. The light beam is reflected back from the mirror to a target region. When the incident and reflected beams are coincident, the cup is aligned for correct placement. The target region is rotatably and pivotably mounted for precise adjustment of the angles of abduction and anteversion respectively.

According to a first aspect of the invention, there is provided apparatus for facilitating aligned location of an acetabular implant in hip joint replacement, comprising frame means for locational juxtaposition adjacent to selected pelvic features of a patient to define a reference plane, means for positioning an acetabular implant in the hip socket, said implant positioning means having an implant mounting portion, and means for determining the disposition of said implant positioning means with respect to said reference plane so that the disposition of an implant mounted on said positioning means relative to said reference plane may be monitored and controlled.

Preferably the frame means has wing portions for juxtaposition adjacent to the anterior superior iliac spines of the pelvis and a further portion or portions for juxtaposition against the pubic tubercles of the pelvis. The apparatus may also incorporate means for affixing said frame means to said features of the pelvis.

Said disposition determining means may include means for emitting a directed beam and target means towards which said beam is directable, correct alignment of the implant positioning means being indicated by impact of the beam on a specified region of the target means. Alternatively detection means such as a plurality of sensors co-operating to provide an output signal on a display

device may substitute for the target means. In an especially preferred embodiment, the disposition determining means includes a reflector such as a mirror mountable on the implant positioning means to reflect said directed beam towards said target means.

In said configuration, the disposition determining means may comprise a light source mounted on the frame means for reflection of said beam back along its initial path when the implant positioning means is correctly aligned. The light source may be a laser source. The apparatus is suitably formed from materials capable of sterilisation without deterioration, or it may be at least partially a disposable unit, the frame for example being discarded after use.

In a further aspect of the invention there is provided apparatus for facilitating aligned location of an acetabular implant in hip joint replacement comprising frame means for locational juxtaposition adjacent to selected pelvic features of a patient to define a reference plane, and means for determining the disposition of an implant positioning means with respect to said reference plane so that the disposition of an implant received on a mounting portion of said implant positioning means relative to said reference plane may be monitored and controlled.

According to an especially preferred embodiment of the invention, there is provided apparatus for facilitating aligned location of an acetabular implant in hip joint replacement comprising frame means for locational juxtaposition adjacent to selected pelvic features of a patient to define a reference plane, and means for determining the disposition of an implant positioning means with respect to said reference plane so that the disposition of an implant received on a mounting portion of said implant positioning means relative to said reference plane may be monitored and controlled, wherein the frame means comprises two foot portions for juxtaposition adjacent to the anterior superior iliac spines of the pelvis and at least one further foot portion for juxtaposition adjacent to one or both pubic tubercles of the pelvis, a central frame region from which limbs extend to said foot portions, and a light-source mounting portion which is pivotably displaceable relative to said central region

of the frame about at least one axis.

The frame is preferably dimensioned so that when said foot portions are juxtaposed against said iliac spines and pubic tubercles, said at least one axis extends substantially perpendicular to a coronal plane defined by these anatomical reference points. The light-source mounting frame portion may have means for receiving a source of collimated light for direction towards a reflector mounted on said implant positioning means, said reflector defining a further portion of the disposition determining means of the apparatus of the invention. The spacing of said foot portions from said central region of the frame may be adjustable to enable use of the apparatus of the invention on a variety of different sizes of patient and under a diversity of operating conditions. The orientation of the foot portions may also be variable relative to the central region of the frame.

The light-source mounting means may comprise a turntable portion which is rotatable relative to said central frame region about said axis generally perpendicular to the coronal plane defined by the anatomical features previously adverted to and engaged by the foot portions in use of the invention. The light-source may be arranged for direction of a light beam substantially at right angles to said perpendicular axis, i.e. generally parallel to the coronal plane in use of the apparatus. The turntable and central region of the frame are preferably calibrated to enable a required angle of abduction to be selected for insertion of an implant cup by rotation of the turntable portion about said at least one axis.

The light-source may be mounted on a faceplate portion and said faceplate portion may be fixed to said turntable portion to extend substantially at right angles from said turntable portion in a plane substantially parallel to said at least one axis of pivoting. This faceplate portion may however also be pivotable relative to the turntable about an axis perpendicular to said at least one axis, thereby enabling variation of the angle of anteversion or retroversion, as required. In this variant of the invention, the faceplate portion may therefore be displaced into dispositions in which it is not parallel to said at least one

substantially perpendicular axis. Preferably calibration means are provided for indicating the relative angular disposition of the faceplate with respect tot he turntable.

A preferred angle of abduction is 45.degree. and a zero angle of anteversion/retroversion is favoured for many applications. The turntable portion is therefore rotated so that the light beam extends from the light-source at a 45 angle of abduction, i.e. generally at 45.degree. relative to the spinal direction of a patient's body. The reflector or mirror is mounted on the implant insertion means in such a way that when the incident reference beam is reflected back on itself by the reflector, the plane of the flat face of the acetabular cup is in the desired orientation with respect to the anatomical reference plane. It therefore then occupies a plane perpendicular to the beam of light.

For use under surgical conditions, the various components of at least the frame of the apparatus of the invention are preferably formed from material capable of ready sterilisation such as stainless steel. It may also be a disposable unit, the frame being formed from, for example, a plastics material, and discarded after one use.

The invention also provides a method for facilitating aligned location of an acetabular implant in hip joint replacement comprising the steps of defining a reference plane by locational juxtaposition of frame means adjacent selected pelvic features of the patient, and determining the disposition of an implant positioning means with respect to said reference plane so that the disposition of an implant received on an implant mounting portion of said positioning means relative to said reference plane may be monitored, controlled and aligned, for correct placement of the implant in the socket of the acetabular.

In a further aspect, the invention also provides training apparatus for placement of an acetabular implant in hip joint replacement, comprising pelvic simulation means having a plurality of features together defining a reference plane, frame means for locational juxtaposition adjacent to said features, and means for determining the disposition of an implant positioning means with respect to said reference plane so that the disposition of an implant received

on a mounting portion of said implant positioning means relative to said reference plane may be monitored and controlled. In a preferred embodiment of this aspect of the invention, said reference plane defining means comprises portions corresponding to the anterior superior iliac spines of the pelvis and at least one further portion corresponding to the pubic tubercles of the pelvis.

Thus the invention provides a system for placing an acetabular cup in total hip arthroplasty at a desired orientation, this orientation being defined with respect to a fixed anatomical reference plane. This plane is preferably defined by the hereinabove recited anatomical points of the pelvis. These features lie in a single coronal plane. The reference beam used in the preferred embodiments of the invention may be any collimated beam, such as a collimated beam of electromagnetic radiation capable of visual detection or detection by other means. The reflector may be any surface capable of reflecting the reference beam, such as a mirror. The orientation of the acetabular cup may be defined by the orientation in space of the plane of the face of the acetabular cup, the curved face of the cup being received within the socket. The frame means or reference frame is attached to or associated with the anatomical features mentioned previously. The implant positioning means or inserter is used by the surgeon to place the acetabular cup in the appropriate cavity in the pelvis.

The beam source is associated with or attached to the reference frame, after this has been attached to or associated with the anatomical features, in such a way that the direction of the collimated reference beam emitted by this source is known with respect to the anatomical features. A reflector is attached to the inserter in such a way that the trigometrical relationship between it and the plane of the face of the acetabular cup is known or defined. The direction of the reference beam relative to the anatomical reference plane and the relationship between the reflector and the plane of the face of the acetabular cup are selected so that when the incident reference beam is reflected, for example, back on itself by the reflector, the plane of the face of the acetabular cup is in the desired orientation with respect to the anatomical reference plane.

Thus the invention has an adjustable frame which is placed over the abdomen of the patient and is firmly located on the four promontories of the

pelvis noted above. The frame acts as a reliable and constant reference plane. The frame carries the source of a narrow beam of electromagnetic radiation, which may be, but is not necessarily, a source of laser emission, and this is directed at a predetermined angle towards a reflector attached to the shaft of a socket holder. The reflector is oriented relative to the shaft of the holder, and the socket, when mounted on the holder, is also aligned, in each case in such a manner that when the reflected beam strikes a target which is located on the reference plane, an which may itself also be the source of the beam, the socket is correctly aligned. The apparatus is arranged so that the position at which the reflected beam strikes the target is visible to the surgeon and is sensitive to the angularity of the socket holding device. The combined effect of the beam, the reflector and the target magnifies angular movement of the socket holder, to enable the surgeon to position the socket consistently to an accuracy within 1.degree. of the optimum angle for cementing the socket into the acetabular. This accuracy represents a considerable improvement on the accuracy usually achievable in the absence of the guidance provided by the invention.

In its training aspect, the invention provides means enabling a surgeon to improve and perfect his implant positioning technique. For this purpose, the implant is aligned and inserted into a receiving portion of a simulated pelvis, which may be either a simplified model of the pelvic structure or an exact reproduction of the pelvic bones. During such training exercises, the entirety of the pelvic model may be draped, so that the surgeon then has to work without a view of the implant site, as is the case in the operating theatre.

The term mirror as used herein in the foregoing definitions of the invention may be regarded as being equivalent to any other form of reflector means, capable of redirecting an impinging electromagnetic beam, such as a light beam. The frame means of the invention is preferably adjustable, so that the relative dispositions of the wing portions and said further portions may be varied to accommodate different dimensions of the pelvic bone structure. The apparatus of the invention may therefore be used for patients of varying sizes and ages.

U.S.P. 6,302,890 to Leone, Jr. discloses a pelvic alignment assembly and method for its use during a total hip replacement surgery in order to accurately re-position the patient's pelvis in a true anterior-posterior or true lateral position so as to optimize the accurate positioning of a prosthetic acetabular cup into the patient's hip joint socket. The assembly includes an elongated pin having one end anchored to the pelvis of the patient and a base removably supported and attached to the opposite, outwardly extending end of the pin. The assembly also includes a mounting member movably connected to the base in a manner which enables the selective adjustment of the relative positions of the base and mounting member in order to dispose a level structure, fixedly secured to the base and movable therewith, into a horizontal position or other predetermined reference orientation. A locking assembly is mounted on the base so as to removably fix the position between the base and the mounting member and maintain the level structure in the predetermined orientation so that the base and mounting member can be removed from the pin. Prior to implanting the acetabular cup into the pelvis, the base, mounting member and level structure are repositioned on the pin and the patient is physically manipulated so as to re-orient the level structure back into the predetermined orientation thereby providing visual indication to the surgeon that the pelvis is re-oriented in the true anterior-posterior or true lateral position.

The alignment assembly comprises an elongated pin such as, but not limited to, a Steinmann pin. The distal end of the elongated pin is specifically structured to be anchored into the pelvis so as to extend outwardly therefrom. The alignment assembly further comprises a base removably mounted on the opposite, outwardly extending, proximal end of the elongated pin, with the base being movably connected to a mounting member. The mounting member includes a socket dimensioned and configured to removably receive the outwardly extending, proximal end of the elongated pin therein, so as to allow stable but removable support and attachment of the base to the elongated pin.

The alignment assembly additionally comprises an adjustment assembly, which is mounted at least in part on the base and which is at least partially

interconnected to the mounting member. The adjustment assembly is specifically designed to be accessed from the exterior of the base, and more specifically, to be manipulated by the surgeon or other medical personnel, so as to selectively adjust the relative position between the base and the mounting member.

The alignment assembly additionally includes a visually observable instrument structured to facilitate the establishment and/or re-establishment of a baseline or reference position of the patient's pelvis in normal or proper anatomical alignment defined by a true anterior-posterior position or true lateral position. The visually observable instrument preferably comprises a level structure that is ideally, but not necessarily, in the form of a "bubble-type" of level secured to the base and moveable therewith. Further, the level structure is disposed on the base in a position which is readily observable by the surgeon and/or other medical personnel in attendance during periods of the surgical procedure, while the base is supported on the proximal end of the pin due to the interconnecting disposition of the mounting member.

In addition, the base of the alignment assembly preferably includes a locking assembly that is operatively connected to the mounting member as well as the base in a manner which is capable of being selectively positioned in either a locked or an unlocked position. The locked position prevents or significantly restricts movement between the base and the mounting member, thereby preventing operation of the adjustment assembly for purposes of changing the position of the base relative to the mounting member. With the locking assembly disposed in the locked position, the surgeon is reasonably assured that the intended position of the level structure relative to the elongated pin may be re-established, when necessary to accomplish the predetermined established anatomical alignment of the pelvis, immediately prior to insertion of the acetabular cup. Further, proper use and observation of the level structure allows the surgeon to re-establish the required pelvic alignment through minimal physical manipulation or repositioning of the patient, immediately prior to the insertion of the acetabular cup into the pelvis.

Use of the alignment assembly of the invention during a THR surgery

involves positioning the patient into a true anterior-posterior or true lateral position on the operating table. After appropriate preparation and draping of the patient, the distal end of the elongated Steinmann pin is anchored to the iliac crest of the patient's pelvis. Initial alignment of the pelvis is accomplished by orienting the elongated pin in an approximately perpendicular relation to the floor, ground or other supporting surface. The base, being movably connected to the mounting member, is supported on the pin by attaching the mounting member to the outwardly extending or proximal end of the pin. While the base remains supported on the pin, the adjustment assembly is manipulated by the surgeon or other medical personnel until the level structure, fixedly secured to the base and movable therewith, indicates that it is oriented into a true horizontal or other applicable reference position. The locking assembly is then manipulated into the locked position, thereby assuring a relative fixed orientation of the level structure relative to the pin, when the base is mounted thereon. The base, along with the mounting member and the level structure, can then be removed from the outwardly extending end of the pin, while the distal end of the pin remains anchored into the pelvis. The surgical procedure associated with a total hip replacement or THR then proceeds to the point where the acetabular cup is ready for insertion into the hip joint socket of the pelvis. Immediately prior to the insertion of the acetabular cup, the base is again supported on the elongated pin by reattaching the mounting member to the proximal end. The locking assembly still maintains the level in its previously, predetermined fixed position relative to the pin. Accordingly, in order to re-orient or position the level structure into the true horizontal or established reference orientation, which was established by locking the mounting member to the base, the patient is then physically moved, such as by rotating the patient, preferably forward or backward, to once again orient the level structure in the predetermined, initially established baseline or reference position. Visual observation of the level structure indicates to the surgeon or other medical personnel, such as when the preferred "bubble" is appropriately located or "centered" within the level structure, that the level structure, the

elongated pin and accordingly, the pelvis is re-oriented in the same, pre-determined established anatomical alignment for optimizing the accurate positioning and insertion of acetabular cup.

THE EXAMINER'S RATIONALE

In objecting to the drawings, the Examiner states that there are two sets of Figures 3A – 3C with the difference that one refers to "the bubble level" (reference "18") and the other refers to "the pelvis level" (reference "18").

In objecting to the disclosure portion of the specification the Examiner states that:

"In page 8, paragraph 0023, reference '18' refers both to 'the bubble level' and 'the pelvis level' (page 10, paragraph 0027). It is noted that reference '28' also refers to 'the pelvis level'.

"In page 8, paragraph 0024, reference '28' refers both to 'the ball level' and 'the pelvis level' (page 10, paragraph 0027).

"The examiner requests clarification between 'the bubble level', 'the pelvis level' and 'the ball level'. For examination purposes, 'the bubble level', 'the pelvis level' and 'the ball level' will be considered as the same embodiment performing the same functions."

In rejecting claims 1 – 2 under 35 U.S.C. 102(b) over U.S.P. 5,141,572 to Farmer et al., the Examiner states that:

"Farmer et al. discloses a pelvis frame comprising: a first rigid elongated member (see Figure 10B below); a second rigid elongated member mounted on the first rigid elongated member in a perpendicular relationship thereto (see Figure 10B below); first and second pads attached to the first rigid elongated member in a perpendicular configuration (see Figure 10B below); a third pad attached to the second elongated member in a perpendicular configuration (see Figure 10B below); and means for varying position of the first, second, and third pads, and for fixating said position as required, for effecting orientation-determining contact of the first, second, and third pads with pelvic bone of the patient; the first, second, and third pads being contoured to conform to portions of the pelvic bone which said pads contact (col. 2, lines 4 – 16; col. 9, lines 14 – 31). The first and second pads include openings (63) for insertion therethrough of first and second wired used to determine the patient's orientation."

In rejecting claims 3 – 6 under 35 U.S.C. 102(b) over U.S.P. 6,302,890 to Leone, Jr., the Examiner states that:

"Leone Jr. discloses a pelvis level comprising: a housing (42) which includes first and second parallel straight-line openings extending therethrough, for insertion therein of first and second wires used to effect temporary connection of the housing to pelvic bone of the patient; and a level (40), disposed in the housing (42) under a transparent cover, for determination of a level position of the housing (col. 6, lines 62-67; col. 7, lines 1-26). The pelvis level (40) is a bubble level (44) comprising a liquid including a bubble, disposed under a convex transparent cover. The pelvis level (40) is a ball level (44) comprising a ball disposed on a concave surface between the transparent cover and the concave surface (col. 6, lines 62-67; col. 7, lines 1-26). The ball, the cover, and the housing (42) are made of a material capable of withstanding steam sterilization. It is noted that it is inherent that the material to be used should be one that is capable of being sterilized, since the pelvis level will be used during a surgical procedure. Further it is noted that it is a matter of design choice whether the bubble or ball level is disposed under a convex transparent cover or concave surface. The level disclosed by Leone, Jr. is capable of performing the functions of the claimed pelvis level.

"With regard to the statement of intended use and other functional statements, they do not impose any structural limitations of the claims distinguishable over Farmer et al. and Leone, Jr. (i.e. 'capable of withstanding steam sterilization') which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore the law of anticipation does not require that the reference 'teach' what the subject patent teaches, but rather it is only necessary that the claims under attack 'read on' something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In rejecting claims 7 – 10 under 35 U.S.C. 103(a) over Farmer et al. in view of Leone Jr., the Examiner states that:

"Farmer et al. discloses a method comprising the steps of: providing a pelvis frame comprising a first rigid elongated member; a second rigid elongated member mounted perpendicularly on the first rigid elongated member; first and second pads attached to the first rigid elongated member; a third pad attached perpendicularly to the second rigid elongated member; and means for varying position of the first, second, and third pads, and for fixating said position as required, for effecting orientation-determining contact of the first, second, and third pads with the patient undergoing the surgery (col. 1, lines 63-67; col. 2, lines 1-3; col. 4, lines 3-14); adjusting the pelvis frame so that the first and second pads rest on the anterior superior iliac spines of the patient undergoing surgery; adjusting the pelvis frame so that the third pad rest on the pubic symphysis of the pelvic bone of the patient undergoing surgery (col. 8, lines 67-68 and col. 9, lines 1-13); drilling first and second wires into the anterior superior iliac spines through first and second opening in the first or second pad contacting the anterior superior iliac spine on the side on which the surgery is to be performed (col. 9, lines 21-31); removing the pelvis frame from contact with the patient; turning the patient from back contact to side contact with an operating-room bed; and beginning the hip-replacement surgery (col. 11, lines 1-22). It is noted that the steps of removing the pelvis frame, turning the patient and beginning hip-replacement surgery would have been inherently carried out as part of the surgical procedure.

"Farmer et al. discloses the claimed invention except for the steps of providing a pelvis level including a level disposed in a housing, which includes first and second parallel straight-line openings extending therethrough; sliding the pelvis level; adjusting position of the operating-room bed; and replacing the acetabular component. Leone, Jr. teaches to provide a pelvis level including a level disposed in a housing, which includes first and second parallel straight-line openings extending therethrough; sliding the pelvis level; adjusting position of the operating-room bed; and replacing the acetabular component (col. 7, lines 48-67; col. 8, lines 1-46) in order to visually observe when the 'bubble' is appropriately located or 'centered' within the level, therefore optimizing the accurate positioning and insertion of the acetabular cup. It would have been obvious to one skilled in the art at the time the invention was made to have the method steps of Farmer et al. including the method steps of providing and sliding the pelvis level as well

as adjusting position and replacing the acetabular component in view of Leone, Jr., in order to visually observe when the 'bubble' is appropriately located or 'centered' within the level, therefore, optimizing the accurate positioning and insertion of the acetabular cup.

"With regards to claims 8-10, Leone, Jr. discloses the limitations, as set forth in column 6, lines 62-67 and column 7, lines 1-26."

REMARKS

The specification/disclosure has been amended by replacing paragraph 0027 on page 10 with a corrected paragraph, and by correcting a typographical error in paragraph 0026.

Claims 1 – 3, 5, and 7 – 9 have been amended to overcome the Examiner's rejection, and to define more clearly what the applicant regards as his invention.

Claim 4, 6, and 10 have been cancelled.

With respect to the Examiner's objection to the drawings, it is respectfully submitted that, in light of the correction of paragraph 0027 of the specification, **FIGS. 4A – 4C** are clearly distinguishable from **FIGS. 3A – 3C**. In **FIGS. 3A – 3C**, the bubble level is generally designated by the numeral **18**. In **FIGS. 4A – 4C**, the ball level is generally designated by the numeral **28**. In **FIGS. 3A – 3C**, the bubble is designated by the numeral **24A**; in **FIGS. 4A – 4C**, the ball is designated by the numeral **33**. These designations are consistent with the corrected paragraph 0027, and with original paragraphs 0011 – 0016 and 0023 – 0024. While the same symbol—a circle—is used to represent both a bubble **24a** and a ball **33**, it is submitted that this representation is correct and consistent, since this would be the appearance of both the bubble **24a** and the ball **33** as viewed in accordance with paragraphs 0011 – 0016. However, if, after considering the above observations and reasoning, the Examiner believes that the drawings require correction, the Examiner is respectfully requested to provide applicant with specific directions or suggestions for making such corrections.

Antecedent basis for amending claim 1 is provided by the specification at paragraph 21, lines 1 – 2, and paragraph 0026, as amended, lines 3 – 6.

Antecedent basis for amending claim 2 is provided by the specification at paragraph 21, lines 1 – 6, and paragraph 0026, as amended, lines 3 – 6.

Antecedent basis for amending claim 3 is provided by **FIGS. 3A – 3C** and **FIGS. 4A – 4C**, and by the specification at paragraph 0027, as amended, lines 12 – 16. It is submitted that a housing inherently has longitudinal and lateral axes, and that a circular level inherently provides orientation along both axes.

Antecedent basis for amending claim 5 is provided by the specification at paragraphs 0014 – 0016 and paragraph 0024, lines 1 – 10.

Antecedent basis for amending claim 7 is provided by **FIGS. 3A – 3C** and **FIGS. 4A – 4C**, and by the specification at paragraph 0027, as amended, paragraph 21, lines 1 – 6, and paragraph 0026, as amended, lines 3 – 6.

Antecedent basis for amending claim 8 is provided by the specification at paragraph 21, lines 1 – 6, and paragraph 0026, as amended, lines 3 – 6.

Antecedent basis for amending claim 9 is provided by the specification at paragraphs 0014 – 0016, and paragraph 0024, lines 1 – 10.

A fee in the amount of $60.00 is tendered herewith, for extension of response within the first month.

APPLICANT'S ARGUMENTS FOR PATENTABILITY

Claim 1 (Currently amended)

As amended, claim 1 specifies that the first and second pads are contoured to conform to the anterior superior iliac spines, and that the third pad is contoured to conform to the pubic symphysis of the patient undergoing hip-replacement surgery.

It is submitted that all three of the pads (feet) (61, 62) disclosed by Farmer et al. are flat, and are therefore not contoured to conform to the iliac spines or to the pubic symphysis of a patient. This observation is supported by and is clearly seen in FIG. 10B, which shows the pads/feet (61 and 62) resting unevenly on the curved iliac spines and on the curved pubic symphysis (tubercules).

Reconsideration, withdrawal of the rejection, and allowance of claim 1 as amended are respectfully requested.

Claim 2 (Currently amended)

As amended, this claim defines the shape of the first and second pads as concave, and the shape of the third pad as saddle-shaped. It will be apparent from FIG. 10B of the Farmer reference that the shapes of the pads as claimed by applicant do indeed conform to the iliac spines and to the pubic symphysis / tubercules, and that the flat pads / feet of the Farmer reference do not.

Reconsideration, withdrawal of the rejection, and allowance of claim 2 as amended are respectfully requested.

Claim 3 (Currently amended)

As amended, claim 3 (paragraph b) recites a circular level including a crosshair, for determining a level position of the level housing along both longitudinal and lateral axes.

It is submitted that the bubble level disclosed by Leone, Jr. is capable of determining a level position along only one axis. In order to determine a level position along a second axis, it would be necessary to reposition the level along that axis. With a circular level, a level position can be determined along both longitudinal and lateral axes without repositioning the level.

Inclusion of a crosshair greatly expands the scope of the circular level. Crosshairs **27a** (**FIGS. 3A** and **3B**) or **37A** (**FIGS. 4A** and **4B**) on the bubble level **18** (**FIGS. 3A – 3C**) or on the ball level **28** (**FIGS. 4A –4C**) are parallel to the coronal plane **15** of the pelvis as depicted in **FIG. 5A**. The crosshairs **27a** (**FIGS. 3A** and **3B**) and **37a** (**FIGS. 4A** and **4B**) therefore provide additional information about pelvic position which is not accounted for by centering the bubble or the ball. (Specification, page 10, replacement paragraph 27.)

Reconsideration, withdrawal of the rejection, and allowance of claim 3 as amended are respectfully requested.

Claim 5 (Currently amended)

As amended, claim 5 specifies that the circular level comprises a ball as the level-determining element.

It is respectfully submitted that, contrary to the Examiner's assertion that "The pelvis level (40) [of the patent to Leone, Jr.] is a ball level (44) comprising a ball disposed on a concave surface between the transparent cover and the concave surface (col. 6, lines 62 – 67; col. 7, lines 1 – 26)," Farmer et al. fail to disclose or even suggest a ball rather than a bubble as a level-determining element. A careful reading of the patent at col. 6, line 62 to col. 7, line 26 fails to reveal any mention whatsoever of a ball. Moreover, the level (40) disclosed by Leone, Jr. at col. 6, lines 62 – 67 and col. 7, lines 1 – 26 is specifically identified and defined thereat as a **bubble** level (col. 6, line 66) having **a sealed outer casing** (42) **partially filled with a liquid and specifically structured to include an air or gas bubble** (44). (Col. 6, lines 66 – 67; col. 7, line1.)

The advantage of a ball level over a bubble level is that the latter requires a gas (usually air) and a liquid (usually water) in a sealed casing. With a ball level, no gas or

liquid is required, and the casing need not be sealed. The only requirement is that the ball be retained within the casing.

Reconsideration, withdrawal of the rejection, and allowance of claim 5 as amended are respectfully requested.

Claim 7 (Currently amended)

As amended, claim 7 (paragraph a) recites "the first and second pads being contoured to conform to anterior superior iliac spines, and the third pad being contoured to conform to pubic symphysis . . .".

The arguments above advanced in support of claim 1 apply to this limitation of claim 7, and are incorporated herein by reference.

Paragraph b recites "a circular level including a crosshair . . ., for determination of a level position of the housing along both longitudinal and lateral axes . . .".

The arguments advanced above to support claim 3 are equally valid with respect to instant claim, and are incorporated by reference.

Paragraph k recites "replacing the acetabular component in the pelvic bone, using the crosshair to determine coronal plane of pelvis."

It is submitted that this step is entirely absent from the procedure described by Farmer et al. or by Leone, Jr. Indeed, such a step is not even suggested by either reference, because the level disclosed by Leone, Jr. does not include a crosshair. As expressed in applicant's arguments above for the allowance of claim 3 as amended, the inclusion of a crosshair greatly expands the scope of the circular level. The reasoning stated thereat is hereby incorporated by reference.

Reconsideration, withdrawal of the rejection, and allowance of claim 7 as amended are respectfully requested.

Claim 8 (Currently amended)

As amended, claim 8 defines the shape of the first and second pads as concave, and the shape of the third pad as saddle-shaped.

The arguments above advanced for the allowance of claim 2 apply with equal force to the present claim. Accordingly, they are incorporated by reference.

Reconsideration, withdrawal of the rejection, and allowance of claim 8 as amended are respectfully requested.

Claim 9 (Currently amended)

As amended, claim 9 recites that the circular level comprises a ball as a level-determining element.

The arguments applied above to claim 5, which prescribes the same limitation, apply equally well to claim 9. Accordingly, said arguments are hereby incorporated by reference.

Reconsideration, withdrawal of the rejection, and allowance of cliam 9 as amended are respectfully requested.

SUMMARY, CONCLUSIONS, AND PETITION

In conclusion, it is submitted that, in view of the amendments, arguments, and reasons above presented, the application is in condition for allowance. Reconsideration, withdrawal of the rejections and objections, and allowance of the application are respectfully requested.

Respectfully submitted

Reginald F. Roberts, Jr.

Reginald F. Roberts, Jr.
Registration No. 29,340
Agent for Applicant
1422 Hearthstone Drive
Baton Rouge, LA 70808-1161

Aug. 1, 2007

Date of Signature